Claims

What is claimed is:

1. A quantitative method of measuring a cardiac function interval, the method comprising:

collecting from a continuous recording of a cardiac interval taken from a single individual obtained over an extended period of time, beat-to-beat data representative of a cardiac interval, each beat-to-beat data having a value,

defining a plurality of bins, each one of the plurality of bins having a defined value range,

organizing each of the collected data into one of the plurality of bins in accordance with the value of the data and the value range of the bin to create a histogram,

constructing a composite histogram by summing the contents of each bin from a set of individual histograms derived from a group of recordings taken from several individuals with common characteristics, and

performing a statistical analysis on the combined histogram to define the statistical characteristics of the group, where such analysis can, but does not necessarily require Gaussian ("normal") distribution of the data in said group.

2. The method of claim 1 wherein the step of summing of each individual bin comprises calculating a composite set of data.

3. The method of claim 1 wherein the representative interval comprises a time measurement.

4. The method of claim 1 wherein the interval comprises an amplitude measurement.

5. The method of claim 1 wherein the step of collecting data comprises obtaining an ambulatory electrocardiographic monitoring recording.

6. The method of claim 1 wherein the cardiac function interval comprises at least one of a QT interval, a QTc interval, a PR interval, an RR interval, an ST interval, a QRS duration, a JT interval, an interval between QTA apex and QTE end of T-wave, and an interval between P beginning and P end.

7. A quantitative method of measuring a cardiac function interval, the method comprising:

collecting from a continuous recording of a cardiac interval taken from a single individual obtained over an extended period of time, beat-to-beat data representative of a cardiac interval, each beat-to-beat data having a value,

defining a plurality of bins, each one of the plurality of bins having a defined value range,

organizing each of the collected data into one of the plurality of bins in accordance with the value of the data and the value range of the bin to create a histogram,

constructing a composite histogram by summing the contents of each bin from a set of individual histograms derived from a group of recordings taken from several individuals with a common characteristics, and

performing a statistical analysis comparing one composite histogram taken from a group of subjects having one common characteristic to a second or more composite histograms taken from a second or more group of subjects having a second or more characteristic to define whether the group or groups have been sampled from the same population.

8. The method of claim 7 wherein the step of summing of each individual bin comprises calculating a composite set of data.

9. The method of claim 7 wherein the representative interval comprises a time measurement.

10. The method of claim 7 wherein the representative interval comprises an amplitude measurement

11. The method of claim 7 wherein the means for collecting data comprises ambulatory electrocardiographic monitor.

12. The method of claim 1 wherein the cardiac function interval comprises at least one of a QT interval, a QTc interval, a PR interval, an RR interval, an ST interval, a QRS duration, a JT interval, an interval between QTA apex and QTE end of T-wave, and an interval between P beginning and P end.

13. A method of measuring an effect of a pharmaceutical or other therapeutic agent on a subject, comprising:

providing a pharmaceutical or other therapeutic agent to the subject,

collecting, over an extended period of time, beat-to-beat data representative of a cardiac interval of the subject, each beat-to-beat data having a value,

defining a plurality of bins, each one of the plurality of bins having a defined value range,

organizing each of the collected data into one of the plurality of bins in accordance with the value of the data and the value range of the bin, and

calculating a sum of data in each bin based upon the quantity of data in each bin to create a composite histogram, and.

statistically analyzing the composite histogram after exposure to the pharmaceutical or other therapeutic agent, baseline or placebo.

14. A quantitative method of measuring a cardiac function interval, the method comprising:

collecting, over an extended period of time, beat-to-beat data representative of a cardiac interval, each beat-to-beat data having a value,

stratifying the collected data, based upon the value of the collected data, in accordance with a plurality of defined bins, each one of the plurality of bins having a defined value range, and

creating a composite histogram to allow statistical analysis of the histogram.

15. A quantitative method of measuring a cardiac function interval, the method comprising:

collecting, over an extended period of time, beat-to-beat data representative of a cardiac interval, each beat-to-beat data having a value,

stratifying the collected data, based upon the value of the collected data, in accordance with a plurality of defined bins, each one of the plurality of bins having a defined value range, and

creating a composite histogram to allow statistical analysis of the histogram, and comparing an individual patient histogram to a composite curve.

16. A method as in claim 15 where the composite curve is derived from a set of normal subjects and the individual histogram is tested to assess the probability that the individual histogram falls within the set of normal subjects.

17. A method as in claim 15 where the composite curve is derived from a set of placebo treated subjects and the individual histogram is tested to assess the probability that the individual histogram falls within the set of placebo subjects.

18. A method as in claim 15 where the comparison of the individual histogram to the composite curve is used as a diagnostic test to determine the probability that the individual is derived from the set utilized to construct the composite curve.

19. A method as in claim 15 where the composite curve is derived from a set of either normal subjects, placebo treated subjects or subjects with other baseline characteristics and the individual histogram is derived from either a potential normal subject or a subject with disease.

Description of the Illustrations

Figure 1. Frequency of QT and QTc intervals in a Normal Subject
Figure 2. Frequency of QT and QTc intervals in a Patient with ILQT
Figure 3. QTc Interval Histogram of a Subject taking Cisapride
Figure 4. Holter Data Comparisons of composite curves from normal subjects, subjects on cisapride and subjects with Inherited Long QT Syndrome (ILQT)
Figure 5. Comparisons Pre/Post Dose of Drug using composite curves (N=19).
Figure 6. Individual Patient with ILQT Compared to a Composite Histogram of Normal Subjects